September 29, 1999

MEMORANDUM

SUBJECT: **TEMEPHOS**: Revised HED Chapter for the Reregistration Eligibility Decision (RED) Document. PC Code: 059001

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The attached Revised HED Chapter of the RED was generated to include the results from a dermal penetration study in rats submitted by the registrant in Phase 3 of the Public Participation Process and responses to comments submitted during the Phase 4 of the Public Participation Process . HED reviewed the study and reassessed the occupational exposure and risk assessment using the updated dermal absorption factor. The registrant needs to work with the Agency on changes and/or clarification of label language. This revised risk assessment includes input from Nicole Paquette (Toxicology), and Jonathan Becker (Occupational Exposure).

Attachments:
Attachment 1: Revised (Phase 4) HED RED Chapter. Nicole C. Paquette, Jonathan Becker (9/29/99)
Attachment 2: HED Review of Dermal Penetration of Radio-labeled Temephos. Nicole C. Paquette (1/27/99)
Attachment 3: Revised (Phase4) Occupational and Residential Exposure Assessment. Jonathan Becker (9/27/99)
Attachment 4: Report of the Hazard Identification Assessment Review Committee. David Liem (5/12/98)

Temephos HED RED CHAPTER

I. EXECUTIVE SUMMARY

The Health Effects Division (HED) has conducted a human health assessment for the active ingredient temephos (O,O,O',O'-tetramethyl O,O'-(thiodi-4,1-phenylene) phosphorothioate, a mosquito larvicide, for purposes of making a reregistration eligibility decision. In making its determination of safety finding for health risks, HED considered potential exposure of occupational workers only, since temephos has no registered food uses or residential uses and therefore, there are no concerns for potential exposures to infants and children. Risk estimates for drinking water were not estimated because Temephos is not expected to reach surface or ground water used for drinking water.

A. Hazard Characterization

The toxicology database for temephos is inadequate with several data gaps. Most of the available studies were conducted in the 1960's and 1970's and do not meet the current requirements of Subdivision F Guidelines. However, the available data are adequate to support the reregistration of temephos for non-food use and non-residential use.

Temephos has relatively low to moderate acute toxicity compared to other organophosphate insecticides. In acute toxicity studies, temephos is more toxic relative to malathion and considerably less toxic relative to ethyl parathion and diazinon. Temephos is moderately toxic by the oral and dermal route, and has low toxicity through inhalation. Signs of toxicity observed in animals treated with high doses of temephos are typical of acute toxicity signs induced by cholinesterase inhibition (ChEI) which include; hypoactivity, labored breathing, rough coat, chromodacryorrhea, salivation, muscle spasms and tremors. Temephos is slightly irritating to eyes but is not a skin irritant or a dermal sensitizer.

In subchronic toxicity studies in rats and dogs, the most sensitive toxicological endpoint is cholinesterase inhibition. Dose-related inhibition of plasma, red blood cell (RBC) and brain cholinesterase (ChE) activity occurs following repeated exposures of various durations. The severity of cholinergic symptoms correlates with the level of inhibition of plasma and RBC ChE activity. Rats are the more sensitive species to ChEI and male rats are the more sensitive sex. In rats, dietary temephos reduced plasma and RBC ChE activity at doses as low as 0.46 mg/kg. In dogs given 12.5 mg/kg of dietary temephos also had reduced plasma and RBC ChE activity and showed cholinergic symptoms after 1 week of dosing which persisted throughout the 90-day study period. In addition to ChEI, the only other systemic effect in subchronic studies was decreased body weight gain in rats. This effect in rats, however, occurred at doses higher (17.5 mg/kg) than the dose which produced ChEI.

A complete assessment of the neurotoxic potential of temephos cannot be made since acute or subchronic neurotoxicity studies in rats are not available. Nevertheless, temephos belongs to the class of organophosphorus insecticides which exert their toxic action by inhibiting cholinesterases in the peripheral and central nervous systems and therefore, neurotoxicity is implied in this class of chemicals.

Temephos is not considered to be a reproductive or developmental toxicant. However, this determination is based in part on a lack of adequate study database and should be viewed as an interim conclusion until more definitive data are available. Since there are no current registered food or residential uses, there are no concerns for potential exposure to infants and children.

Temephos is not classified as a carcinogen mainly because of the inadequate database, therefore, the cancer potential was not presented in this risk assessment. The only study available was a 2- year chronic study in rats, in which the highest dose (15 mg/kg) did not induce tumor formation. In addition, several *in vitro* mutagenicity studies were considered not adequate to evaluate the genotoxic potential of temephos. Because this chemical is for non food use only, a chronic/ carcinogenicity study in another species is not required.

B. Exposure Characterization

Temephos is used as a mosquito larvicide for application to aquatic non-crop sites. The use sites include outdoor non-food and non-domestic aquatic areas such as standing waters (tidal areas, woodland pools, shallow ponds, tire and refuse piles), ponds, lakes, tidal waters, catch basin, marshlands, margins of streams, and intertidal zones of sandy beaches. These use sites are typically polluted or saline waters and are therefore, are unusable as a source of drinking water.

Temephos is formulated as a granular and as an emulsifiable concentrate. It can be applied by fixed-wing aircraft, helicopter, hand-held sprayers, power backpack blowers, and by spoon. Application rates are based on the organic content of the standing water being treated and range up to 0.5 lb ai per acre for granular formulations and up to 0.0469 lbs ai per acre (1.5 fl.oz. per acre) for the emulsifiable concentrate. Areas can be treated multiple times per year, as needed.

Potential occupational exposure routes for handlers are dermal and inhalation and may be of short-term (1 to 7 days), intermediate-term (1 week to several months), and chronic durations (more than several months).

HED has identified 14 major scenarios for which there are potential for occupational exposure. The use of maximum PPE and engineering controls results in MOEs greater than 100 for most scenarios: mixing / loading liquids for aerial application, mixing /loading for rights-of-way sprayer, loading granulars for aerial application, applying liquids using fixed-wing aircraft, applying liquids using a rights-of-way sprayer, flagging during aerial application of granulars and liquid sprays, mixing / loading / applying sprays with a backpack sprayer, and applying granulars

by spoon. Two exposure scenarios lack data and occupational risks could not be assessed. Two occupational exposure scenarios have MOEs are less than 100 and exceed HED's level of concern despite maximum mitigation measures and include applying granulars using fixed-wing aircraft, and applying granulars with a belly grinder.

HED believes that it is unlikely that significant postapplication exposures would occur based on the low application rate (0.5 lb ai per acre for granular formulations; 0.0469 lb ai per acre for liquid formulations), the short duration spent by the worker in a treated area, and the low exposure activities performed by the worker.

There are no residential uses of temephos. Because of the areas in which temephos is aerially applied (e.g., tidal marshes) and the presumed large droplet size of the spray, HED believes it is unlikely that significant exposure via spray drift would occur. However, because of the diversity of sites that temephos may be used, HED is concerned that bystander spray drift exposure may occur in some situations. Although temephos may be used in areas (e.g., temporary pools along the side of the road, standing water in discarded tires, and refuse piles) that may occasionally be visited by the general population, HED believes that postapplication exposure would be minimal. This belief is based on the low application rate, the likelihood of a brief duration spent in such environments, and the probability of low exposure activities of the residents.

C. Risk Characterization

Risks of Concern: Occupational combined dermal and inhalation MOEs of less than 100 for short-term exposure, intermediate term and chronic term exposure durations are considered to be of risk concern. Calculations of occupational risk were based on combined dermal and inhalation exposures, a No Observable Adverse Effect Level (NOAEL) = 0.3 mg/kg/d, and 38% dermal absorption and 100% inhalation absorption.

- Occupational handler combined dermal and inhalation baseline MOEs range from 0.58 to 280 for short-term, intermediate-term and chronic exposures. The MOEs of concern are not mitigated by the addition of PPE or engineering controls in two scenarios: applying granulars using fixed-wing aircraft, and applying granulars with a belly grinder.

The MOEs estimated for all-occupational exposure scenarios indicates that there is a risk concern for currently registered uses of temephos. These MOE calculations were based on inhibition of plasma ChE activity in subchronic oral toxicity study in the rat.

D. Aggregate Risk

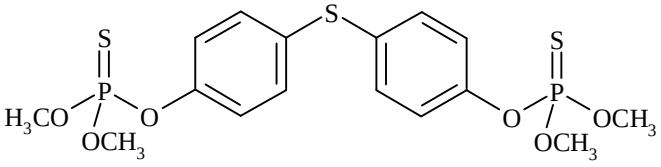
Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources, specifically, drinking water and residential. There is no risk concern for drinking water exposure because temephos is applied to shallow, brackish polluted waters which are unsuitable for human consumption. The Environmental Fate and Effects Division (EFED) does not expect temephos to reach ground water (used for drinking water) because of the lack of hydraulic gradient and the short half-life. Since residential exposure to temephos is not a risk concern, a quantitative aggregate exposure assessment for drinking water and residential is not required.

II SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

1. Identification of Active Ingredient

Pure temephos is a white crystalline solid with a melting point of 30°C; technical temephos is a brown viscous liquid which decomposes at 120-125°C, and has a specific gravity of 1.3, an octanol/water partition coefficient of 80,900 and vapor pressure of 7.17×10^{-8} mm Hg at 25°C. Technical temephos is essentially insoluble in water (0.03 ppm), and is insoluble in hexane and methyl cyclohexane. Temephos is soluble at 100g/100 mL in acetone, acetonitrile, dichloromethane, and toluene at 20°C. It is also soluble in carbon tetrachloride, chloroform, diethyl ether, ethytlene dichloride, and lower molecular weight alkyl ketones.



Empirical Formula:	$C_{16}H_{20}O_6P_2S_3$
Molecular Weight:	466.4
CAS Registry No.:	3383-96-8
PC Code:	059001

2. Manufacturing-Use Products

A search of the Reference Files System (REFS) conducted 6/24/98 identified a single temephos manufacturing-use product (MP) registered under PC Code 059001: the Clarke Mosquito Control Products Inc. 90% technical (T; EPA Reg. No. 8329-56). The Clarke Mosquito Control Products 90% T was transferred from American Cyanamid Company (EPA Reg. No. 241-

220) on 9/9/97. Only the Clarke Mosquito Control Products 90% T is subject to a reregistration eligibility decision.

3. Product Chemistry Data

Most product chemistry data requirements remain outstanding for the Clarke Mosquito 90% T. Provided that the registrant submits the data required in the attached data summary table for the 90% T, and either certifies that the suppliers of beginning materials and the manufacturing process for the temephos technical product/MP have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of temephos with respect to product chemistry data requirements.

B. Hazard Profile

1. Hazard Assessment

The toxicological data base for temephos is inadequate to support reregistration. However, the available data are adequate to support the non-food use/non-residential use pattern.

a. Acute Toxicity

Table 1. Summary of acute toxicity data for temephos.

Guideline#	Study Type	MRID	Results	Toxicity Category
870.1100	Acute Oral (Rats)	00001902	LD_{50}= 444 mg/kg	II
870.1200	Acute Dermal (Rabbits)	140124 1906/1907	LD_{50} = 1850 mg/kg (Males) LD_{50} = 970 mg/kg (Females)	II II
870.1300	Acute Inhalation	00101656	LC_{50} > 1.3 mg/L	III
870.2400	Primary Eye Irritation	001907	Corneal opacity 72 hrs	III
870.2500	Primary Skin Irritation	140124	PIS = 1.4	IV
870.2600	Dermal Sensitization	00157836	Not a sensitizer	

b. Dermal Absorption

No acceptable guideline dermal absorption studies are available. Dermal studies conducted in rabbits are not considered adequate. Dermal rabbit studies can be expected to underestimate the toxicity of sulfur-containing organophosphates because rabbit blood has high concentrations of arylesterases, a class of enzymes which detoxify the compounds before they can be converted to the activated form in the liver. For this reason, the rat is the preferred species for dermal studies.

On November, 2, 1998, the registrant submitted a published dermal absorption study of temephos (MRID 44756801) conducted by the Department of the Army as part of the *Phase 3 - 60 Day Public Comment on EPA's Temephos Draft Health Effects Division Chapter of the Reregistration Eligibility Decision Document* (September 9, 1998). The Health Effects Division reviewed the study (HED Doc No.:013241) and a dermal absorption factor of 38% was used in this assessment.

c. Summary of Toxicology Endpoints Selection

Table 2. The doses and toxicological endpoints selected for various exposure scenarios are summarized below.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY	MOE
Acute Dietary	None	No registered food or residential uses; risk assessment is not required.		NA
Chronic Dietary	None	No registered food or residential uses; risk assessment is not required.		NA
Short-Term (Dermal) [a]	Oral NOEL= 0.3	RBC ChE Inhibition at 0.9 mg/kg/d at Week 1	90-day Feeding Study in Rats	100
Intermediate-Term (Dermal) [a]	Oral NOEL= 0.3	RBC ChE Inhibition at 0.9 mg/kg/d	90-day Feeding Study in Rats	100
Long-Term (Dermal)	Oral NOEL= 0.3	RBC ChE Inhibition at 0.9 mg/kg/d	90-day Feeding Study in Rats	100
Inhalation (Any Time Period)[a]	Oral NOEL= 0.3	RBC ChE Inhibition at 0.9 mg/kg/d	90-day Feeding Study in Rats	100

a = Since an oral NOEL was selected a dermal absorption (38%) and inhalation absorption (100%) factors should be used for these risk assessments (i.e., corrected for dermal and inhalation exposures).

d. Response to Comments Regarding the Dermal Absorption Factor

During the Public Participation Process (Phase4), the United States Department of Agriculture (USDA) submitted comments to the public docket concerning the Agency's Preliminary Human Health Risk Assessment for Temephos. The USDA objected to EPA's dermal absorption factor of 38% (from published study) stating that the conclusion was ten times more conservative than the US Army conclusion of a 3% dermal absorption estimate.

The 3% dermal absorption factor was an estimate discussed by the study author of the US Army study was not derived from actual experimental data in dogs, rabbits or rats. EPA's conclusion of 38% dermal absorption was calculated using experimentally derived values from the submitted non-guideline study using the rat. While the rat was not intended as a model of dermal absorption to predict penetration through the human skin, the rat has been extensively used for metabolic and toxicological studies and allows for consistency and comparisons from study to study and the Agency believes it is reasonable to use the rat as the preferred species for dermal absorption studies. Furthermore, it is not HED's policy to compare relative dermal absorption across species because there is considerable species variation in dermal penetration and subsequent toxic responses to toxicants due to inherent physiological differences. Converting dermal absorption from one animal species to another and applying that data to humans is met with caution.

e. Determination of the FQPA Safety Factor

The FQPA Safety Committee determined that the 10X for temephos should be retained solely because of the inadequacy of the toxicology data base which precluded an evaluation of potential enhanced susceptibility to infants and children. However, an FQPA safety factor for the protection of infants and children from exposure to temephos is not necessary because presently there are no registered food, drinking water or residential uses and thus there are no concerns for potential exposures of infants and children to temephos.

C. Occupational Exposure and Risk Assessment

Temephos is formulated as a granular (1 to 5 percent active ingredient) and as an emulsifiable concentrate (40 to 45 percent active ingredient). It is used to control mosquito larvae in standing water (tidal areas, woodland pools, shallow ponds, tire and refuse piles). It can be applied by fixed-wing aircraft, helicopter, hand-held sprayers, power backpack blowers, and by spoon. Application rates are based on the organic content of the standing water being treated and range up to 0.5 lb ai per acre for the granular formulation and up to 0.469 for the liquid. Areas can be treated multiple times per year, as needed.

Potential occupational exposure routes are dermal and inhalation and may be of short-term (1 to 7 days), intermediate-term (1 week to several months), and chronic durations (more than several months). The largest United States end user of temephos (Lee County Mosquito Control District, Florida) reports that in a "typical" year they apply temephos 5 to 6 days per week from May through October and possibly 2 days per week for the rest of the year (about 160 applications per year). Variation in amount of rainfall in a specific geographical region can greatly prolong or shorten the

seasonal duration of required mosquito larvicide treatments. There are no homeowner uses of temephos.

1. Occupational Exposure

Application Rates: Temephos may be applied up to 0.5 lbs a.i. per acre for granular formulations and up to 0.04688 lbs a.i. per acre for liquid formulations.

Submitted Studies: HED is not aware of any handler exposure study submitted to the Agency for review.

Handler Exposure Scenarios: HED has identified the potential for occupational exposure for 14 major scenarios, as follows: (1) mixing / loading liquids for aerial application; (2) mixing / loading liquids for rights-of-way sprayer; (3) loading granulars for aerial application; (4) applying liquids using fixed-wing aircraft; (5) applying liquids using helicopter; (6) applying liquids using rights-of-way sprayer; (7) applying granulars using fixed-wing aircraft; (8) applying granulars using helicopter; (9) flagging during aerial application of liquid sprays; (10) flagging during application of granulars; (11) mixing / loading / applying sprays with a backpack sprayer; (12) loading / applying granulars with a power backpack blower; (13) loading / applying granulars with belly grinder; and (14) applying granulars by spoon.

Occupational handler dermal and inhalation exposures for all durations (developed using PHED Version 1.1 surrogate data) are presented in the attached spreadsheet. The assumptions and the formulas that were used in the exposure / risk calculations are as follows:

- Daily exposure (mg/day) = Unit exposure (mg/lb ai) * Application rate (lb ai/acre) * Acres treated.
- Acres treated are 350 to 700 acres per day for aerial application, 40 acres per day for rights-of-way sprayer, and 5 acres per day for backpack sprayer. Based on flight logs from 1996 supplied by the Lee County, a greater number of acres may be treated by air on some occasions, for example 1024 ac Mosquito Abatement District res treated in 4.5 hours by a single applicator on May 23, 1996 and 1482 acres treated in 5.3 hours by a single applicator on August 8, 1996.
- Daily dose (mg/kg/day) = Daily exposure (mg/kg) / Body weight (70 kg).
- MOE = NOEL (mg/kg/day) / Daily dose (mg/kg/day).
- Body weight for an adult handler is assumed to be 70 kg.
- PHED clothing and risk mitigation scenarios are as follows: Baseline - long sleeved shirt, long pants, no respirator; Maximum PPE - coveralls over long pants, long sleeved shirt, chemical-resistant gloves, organic vapor respirator; Engineering Controls - long pants, long sleeved shirt, no gloves in an enclosed cab or cockpit, closed mixing/loading.
- Data from PHED for helicopter application of sprays and granulars are based on a very limited number of replicates. Instead of assessing this exposure scenario using inadequate data, data from PHED for fixed-wing application of sprays were used in accordance with HED Science Advisory Council of Exposure Policy Number 5 (May 7, 1998).

- Application rates in Florida may typically be less than the maximum rate permitted on the lables. These lower rates have been well documented by the Lee County Mosquito Abatement District. EPA's occupational risk assessment reflects the higher rates that are currently on the label.

Handler Exposure Scenario Results: Results for the occupational handler scenarios are presented in the attached spreadsheet and are summarized below in Table 3.

Table 3. Highest estimated MOE for each temephos exposure scenario for all exposure durations.

Exposure Scenario	Range of MOEs		
	Baseline	Maximum PPE	Engineering Controls
Mixer/Loader			
Mixing / loading liquids for aerial application	0.58 - 1.2	97 - 190	190 - 380
Mixing / loading liquids for rights-of-way sprayer	10	1,700	3300
Loading granulars for aerial application	12 - 25	41 - 82	610 - 1,200
Applicator			
Applying liquids using fixed-wing aircraft	No data	Scenario not feasible	330 - 650
Applying liquids using helicopter	No data	Scenario not feasible	No adequate data
Applying liquids using rights-of-way sprayer	22	100	Scenario not feasible
Applying granulars using fixed-wing aircraft	No data	Scenario not feasible	31 - 63
Applying granulars using helicopter	No data	Scenario not feasible	No data
Flagger			
Flagging during aerial application of liquid sprays	140 - 280	170 - 330	7,700 - 14,000
Flagging during application of granulars	49 - 99	96 - 190	2,500 - 4,900

Exposure Scenario	Range of MOEs		
	Baseline	Maximum PPE	Engineering Controls
Mixer/Loader/Applicator			
Mixing / loading / applying sprays with a backpack sprayer	91	150	Scenario not feasible
Loading / applying granulars with a power backpack blower	No data	No data	Scenario not feasible
Loading / applying granulars with belly grinder	2.2	2.7	Scenario not feasible
Applying granulars by spoon (by hand used as a surrogate)	66	120	Scenario not feasible

Postapplication Exposure Scenarios: HED believes that postapplication exposures would be minimal. This belief is based on the low application rate (0.5 lb ai/acre or less) of temephos, the short duration spent by the worker in a treated area (typically a few minutes), and the low exposure activity of the worker (typically dipping water from a temporary pool with a long handled dipper and examining the collected water for mosquito larvae).

Cholinesterase Monitoring: The Lee County Mosquito Control District submitted limited monitoring data from their cholinesterase testing program to the Agency. Data were submitted for four job categories – inspector, aircraft mechanic, mixer/loader, and pilot. Each job category was represented by one individual. Blood samples were taken at intervals of approximately six months to one year from 1993 to 1995 yielding three or four samples per individual. Plasma and red blood cell cholinesterase levels were measured and expressed as a percentage of the reference range. For plasma cholinesterase "normal" values range from 42 to 158 percent and for red blood cell cholinesterase "normal" values range from 71 to 130 percent of the reference level. Summarized results for these four individuals are presented in Table 4.

Table 4. Results of cholinesterase sampling of four individuals (1 or 2 samples per year) representing four different job categories.

Job Category	Number of Samples	Sample Years	Plasma ChE (% of Reference Range)	Red Blood Cell ChE (% of Reference Range)
Inspector	4	1993 – 1995	115 – 125	106 – 120
Aircraft Mechanic	3	1993 – 1995	78 – 85	96 – 104
Mixer / Loader	3	1993 – 1994	70 – 114	98 – 114
Pilot	3	1993 - 1994	80 – 98	114 – 124

The data in Table 4 show that the cholinesterase levels of the four individuals tested from 1993 to 1995 were within the reference range for the general population in the United States for all samples. These data have limited utility in addressing the cholinergic effects of organophosphate pesticides, specifically temephos, on the workers for the following reasons:

- Representativeness of four individuals to other member of the same job category is not established.

- Complete occupational exposure history to organophosphate pesticides or other cholinesterase inhibiting chemicals is not known.

- Baseline plasma and red blood cell cholinesterase levels were not established for each individual. A non-exposed (control) group was not included.

- The health histories of subjects are not know.

2. Residential Exposure

Residential Handler Exposure: There are no residential uses of temephos. Because of the areas in which temephos is aerially applied (e.g., tidal marshes) and the presumed large droplet size of the spray, it is unlikely that significant exposure via spray drift would occur. However, because of the diversity of sites that temephos may be used, HED remains concerned that bystander spray drift exposure may occur in some situations. HED reserves the decision concerning the magnitude of bystander spray drift exposure and the required buffer zone until data can be supplied.

Residential Postapplication Exposure: Although temephos may be used in areas (e.g., temporary pools along the side of the road, standing water in discarded tires, and refuse piles) that may occasionally be visited by the general population, HED believes that it is unlikely that significant postapplication exposure would occur. This belief is based on the low application rate, the likelihood of a brief duration spent in such environments, and the probability of low exposure activities of the residents.

Incident Reports: A search for incident data by Jerome Blondell (OPP/HED/CEB2) did not identify any cases of temephos related illnesses or injuries. This may be due to the relatively small amount of temephos used (as compared to other organophosphate pesticides).

3. Summary of Risk Concerns for Occupational Exposures

Based on the above occupational exposure and risk assessment, HED concludes:

- The use of risk mitigation measures for occupational handlers (i.e., maximum PPE and engineering controls) results in **MOEs greater than 100** for the following scenarios: mixing / loading liquids for aerial application, mixing /loading for rights-of-way sprayer, loading granulars for aerial application, applying liquids using fixed-wing aircraft, applying liquids using

a rights-of-way sprayer, flagging during aerial application of granulars and liquid sprays, mixing / loading / applying sprays with a backpack sprayer, and applying granulars by spoon.

- The use of risk mitigation measures form occupational handlers (i.e., maximum PPE and engineering controls) results in **MOEs less than 100** for the following scenarios: applying granulars using fixed-wing aircraft,and loading / applying granulars with belly grinder.

- Two scenarios lack exposure data that are needed to assess risk to temephos handlers. These scenarios are applying granulars using a helicopter and loading / applying granulars with a power backpack blower. A power backpack blower is frequently the method of choice for applying granulars to tire piles.

- HED remains concerned that bystander spray drift exposure may occur in some situations and requests supporting data concerning bystander spray drift exposure from the registrant.

III. CONCLUSION

Temephos, formulated as a granular and as an emulsifiable concentrate, is used as an insecticide for the control of mosquito larvae. Based on HED's occupational risk assessment, MOEs are less than 100 for two exposure scenarios. Exposure scenarios with MOEs greater than 100 include mixing / loading liquids for aerial application, mixing /loading for rights-of-way sprayer, loading granulars for aerial application, applying liquids using fixed-wing aircraft, applying liquids using a rights-of-way sprayer, flagging during aerial application of granulars and liquid sprays, mixing / loading / applying sprays with a backpack sprayer, and applying granulars by spoon. Two exposure scenarios could not be assessed because of the lack of exposure data. HED also requests supporting data concerning bystander spray drift exposure from the registrant. A drinking water risk assessment is not required because, temephos is applied to water that cannot be used as a source of surface water/drinking water and is not expected to reach ground water that would be used for drinking water because of the lack of a substantial hydraulic gradient and the short half-life of temephos.

IV DATA REQUIREMENTS

a. <u>Toxicology</u>

▸ 21-Day Dermal Toxicity Study in Rats (with blood cholinesterase meaurements at earlier time point within the first 7 days)	870-3200
▸ Developmental Toxicity -Rat or Rabbit	870.3700

b. Occupational and Residential Exposure

The Agency would like to meet with the registrant to discuss the need for the following data:

- Supporting data concerning bystander spray drift exposure.
- Occupational exposure data for application of granulars by helicopter
- Occupational exposure data for application of granulars by power back pack blower